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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,250	01/12/2005	Rene Cornford-Nairn	21415-0010US1	8940

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EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/500,250	CORNFORD-NAIRN ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20,21 and 23-41* is/are pending in the application.

4a) Of the above claim(s) *40 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18,20,21 and 23-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I claim(s) 2-15, 34, 35, and 37, drawn to a genetically modified *Bordetella avium* having a partial or complete loss of function in the endogenous aroQ gene and a lower capacity to propagate in a mammalian host but remaining viable in the host for a period of time sufficient to induce an immune response against a pathogenic *Bordetella avium*.

Group II claim(s) 2-15, 34, 35, and 37, drawn to a genetically modified *Bordetella bronchiseptica* having a partial or complete loss of function in the endogenous aroQ gene and a lower capacity to propagate in a mammalian host but remaining viable in the host for a period of time sufficient to induce an immune response against a pathogenic *Bordetella bronchiseptica*.

Group III claim(s) 2-15, 34, 35, and 37, drawn to a genetically modified *Bordetella holmesii* having a partial or complete loss of function in the endogenous aroQ gene and a lower capacity to propagate in a mammalian host but remaining viable in the host for a period of time sufficient to induce an immune response against a pathogenic *Bordetella holmesii*.

Group IV claim(s) 2-15, 34, 35, and 37, drawn to a genetically modified *Bordetella parapertussis* having a partial or complete loss of function in the endogenous aroQ gene and a lower capacity to propagate in a mammalian host but remaining viable in the host for a period of time sufficient to induce an immune response against a pathogenic *Bordetella parapertussis*.

Group V claim(s) 2-15, 34, 35, and 37, drawn to a genetically modified *Bordetella pertussis* having a partial or complete loss of function in the endogenous aroQ gene and a lower capacity to propagate in a mammalian host but remaining viable in the host for a period of time sufficient to induce an immune response against a pathogenic *Bordetella pertussis*.

Group VI, claim(s) 16-18, and 20, drawn to an isolated polynucleotide comprising a nucleotide sequence that corresponds or is complementary to at least a portion of the sequence set forth in SEQ ID NO: 1 or 3, which portion is at least 50 nucleotides in length.

Group VII, claim(s) 21, 23, and 24, drawn to an isolated polypeptide comprising an amino acid sequence that has at least 70% sequence identity to at least a portion of the sequence set forth in SEQ ID NO: 2.

Group VIII, claim(s) 25, 26, and 29, drawn to a nucleic acid construct for disrupting an aroQ gene in a Bordetella cell, wherein the aroQ gene comprises the sequence set forth in SEQ ID NO: 1 or 3 or a variant or derivative thereof.

Group IX, claim(s) 27-29, drawn to vectors comprising a nucleotide sequence that corresponds or is complementary to at least a portion of the sequence set forth in SEQ ID NO: 1 or 3, and host cells containing said vector.

Group X, claim(s) 30, drawn to an antigen-binding molecule that is specifically interactive with the polypeptide.

Group XI, claim(s) 31-33, drawn to a method for producing a genetically modified Bordetella strain, comprising introducing a nucleic acid construct into a Bordetella cell under conditions such that the nucleic acid construct is homologously recombined into the aroQ gene in the genome of that cell to produce a genetically modified Bordetella cell containing a disrupted aroQ gene.

Group XII, claim(s) 36, drawn to a composition of matter comprising dendritic cells which have been exposed to the genetically modified Bordetella strain of having a partial or complete loss of function in the endogenous aroQ gene and a lower capacity to propagate in a mammalian host but remaining viable in the host for a period of time sufficient to induce an immune response against a pathogenic Bordetella strain for a time and under conditions sufficient to express a processed or modified antigen derived from the Bordetella strain for presentation to, and modulation of, T cells.

Group XIII, claim(s) 38 and 41, drawn to a method for modulating an immune response, comprising administering to a patient in need of such treatment an effective amount of the genetically modified Bordetella strain a partial or complete loss of function in the endogenous aroQ gene and a lower capacity to propagate in a mammalian host but remaining viable in the host for a period of time sufficient to induce an immune response against a pathogenic Bordetella strain.

Group XIV, claim(s) 39, drawn to a method for the treatment and/or prophylaxis of whooping cough or related condition, comprising administering to a patient in need of such treatment an effective amount of the genetically modified Bordetella strain of a

partial or complete loss of function in the endogenous aroQ gene and a lower capacity to propagate in a mammalian host but remaining viable in the host for a period of time sufficient to induce an immune response against a pathogenic Bordetella strain.

Claim 1 is a linking claim, linking the invention of claims 3 and 4. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 40 is drawn to use claims and have been withdrawn from further consideration.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I)

comprises the first recited **product**, a genetically modified Bordetella strain having a partial or complete loss of function in the endogenous aroQ gene and a lower capacity to propagate in a mammalian host but remaining viable in the host for a period of time sufficient to induce an immune response against a pathogenic Bordetella strain. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The special technical feature of Group I is the genetically modified *Bordetella avium*.

The special technical feature of Group II is the genetically modified *Bordetella bronchiseptica*.

The special technical feature of Group III is the genetically modified *Bordetella holmesii*.

The special technical feature of Group IV is the genetically modified *Bordetella parapertussis*.

The special technical feature of Group V is the genetically modified *Bordetella pertussis*.

The special technical feature of Group VI is an isolated polynucleotide comprising a nucleotide sequence that corresponds or is complementary to at least a portion of the sequence set forth in SEQ ID NO: 1 or 3, which portion is at least 50 nucleotides in length.

The special technical feature of Group VII is an isolated polypeptide comprising an amino acid sequence that has at least 70% sequence identity to at least a portion of the sequence set forth in SEQ ID NO: 2.

The special technical feature of Group VIII is the nucleic acid construct wherein the aroQ gene comprises the sequence set forth in SEQ ID NO: 1 or 3 or a variant or derivative thereof.

The special technical feature of Group IX is a vector comprising a nucleotide sequence that corresponds or is complementary to at least a portion of the sequence set forth in SEQ ID NO: 1 or 3, and the host cells containing said vector.

The special technical feature of Group X is an antigen-binding molecule.

The special technical feature of Group XI is the steps used for producing a genetically modified Bordetella strain.

The special technical feature of Group XII is the matter comprising dendritic cells.

The special technical feature of Group XIII is the steps for modulating an immune response.

The special technical feature of Group XIV is the steps for the treatment and/or prophylaxis of whooping cough or related condition.

These inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In addition, Groups VI, VIII, and IX, detailed above, read on patentably distinct to genes using different SEQ ID numbers and are structurally different with differing biochemical and immunological properties.

A further restriction is applied to each group. Applicant must further elect one of the following inventions:

a) SEQ ID NO: 1

b) SEQ ID NO: 3

Applicant is advised that examination will be restricted to only the elected sequence and should not be construed as a species election.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LET
11/28/06

ROBERT A. ZEMAN
PRIMARY EXAMINER